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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

22264 U.S. PTO 60/559779

INVENTOR(S)

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☐ *Additional inventors are being named on th____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

METHOD FOR ENCAPSULATION OF ORALLY INGESTED MATERIALS TO ALTER THE SITE OF DIGESTION, SITE OF ACTION, OR STABILITY

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 4 ☐ CD(s), Number

☐ Drawing(s) *Number of Sheets* ☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☒ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check or money order is enclosed to cover the filing fees

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Respectfully submitted,

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TELEPHONE 816/474-9050

Date 04/06/04

REGISTRATION NO. *(if appropriate)* 43,205

Docket Number: 34785-PRO

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Docket No. 34785-PRO
Drouillard et al	
Serial No. :	Group Art Unit No.
Filed:	
METHOD FOR ENCAPSULATION OF ORALLY INGESTED MATERIALS TO ALTER THE SITE OF DIGESTION, SITE OF ACTION. OR STABILITY	Examiner:

Commissioner of Patents
Alexandra, VA 22313-1450

Sir:

TRANSMITTAL

Transmitted herewith are: Express Mail Transmittal (1 Page); Provisional Transmittal (1 page); Specification (4 pages); $80.00 fee; and return postcard.

EL 993327268 US

Respectfully submitted,

Date: April 6, 2004

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METHOD FOR ENCAPSULATION OF ORALLY INGESTED MATERIALS TO ALTER THE SITE OF DIGESTION , SITE OF ACTION, OR STABILITY

BACKGROUND OF THE INVENTION

Research experiments with beef cattle, demonstrated that feeding an encapsulated form of choline (a B-vitamin) improved the performance and carcass quality of finishing beef cattle. The choline used in these experiments was encapsulated with stearic acid, which is a saturated fatty acid that is relatively resistant to degradation by ruminal microorganisms. However, the cost of the stearic acid coating and its associated manufacturing process was relatively high. Therefore, this practice has not proven cost effective.

Experiments have also been conducted to evaluate zein-based films as protective barriers to reduce ruminal digestion of nutrients. In the zein (corn protein) trials, the product was mixed with ethanol as a solvent. The zein/ethanol mixture was initially combined with soybean meal (as a test material to determine efficacy of encapsulation), dehydrated, and later subjected to ruminal fermentation. Zein was reasonably effective as a protective barrier, but as with stearic acid, the cost was too high to be commercially viable.

Therefore, there is a real and unfulfilled need in the art for a protein-based film capable of encapsulating orally ingested materials so as to alter the site of digestion of the materials within the stomach of an animal.

SUMMARY OF THE INVENTION

In one aspect of the present invention, a proteinaceous film is provided that, when applied to the exterior surface of comestible particles, provides a protective barrier that renders the particles more resistant to microbial digestion within the forestomach of ruminants, such as cattle or sheep. By applying this technology to vitamins, minerals, proteins, carbohydrates, lipids, antimicrobials, and/or other drug compounds, it is feasible to deliver said compounds intact to the small intestine, thus improving likelihood of adsorption. In so doing, it is possible to improve efficiency of nutrient and/or drug utilization by selecting sites of digestion and adsorption that are more consistent with optimization of animal health and production.

The protective barrier is created by preparing a solution containing 1 to 50% by weight of a large, soluble, film-forming biomolecule, such as a vital wheat gluten, wheat protein isolate, other derivatives of wheat protein, zein protein, and soy protein, in a solute such as water or ethanol. Acetic acid, hydrochloric acid, or other pH modifiers also may be used with the present invention. Particulate matter, consisting of vitamins, minerals, amino acids, drugs, nutriceuticals, or other food ingredients, are then added to the solution and blended to form a homogeneous mixture. The mixture is then dried via vacuum drying, spray-drying, freeze-drying, or even oven-drying to remove excess solute. The resulting dried material comprises the particulate matter encapsulated by a proteinaceous film. This film, when exposed to the rumen environment, is substantially resistant to microbial degradation, thereby preventing access to the material encapsulated within.

Another aspect of the present invention comprises coating particles to prevent interaction with other components of a mixture. For example, coating of vitamins with a protective barrier may prevent premature oxidation by mineral elements included in the same mixture. Furthermore, since stability of the films is dependent on pH, this property may be exploited in food systems, such as with pH-dependent release of reagents in fermented food products, or in the digestive tracts of animals for the targeted release of encapsulated materials within specific sites of the gastrointestinal tract.

The protein-based films are also useful as barriers to prevent interactions among ingredients within mixtures, thus preserving their integrity and/or shelf stability. Furthermore, the present invention provides an alternative to current methods for stabilization of vitamins used in humans, ruminants, non-ruminant livestock, aquatic species, and poultry. Currently, many vitamins are stabilized using gelatin beadlets. Incidents involving the discovery of Bovine Spongiform Encephalopathy (BSE or "mad cow disease") in cattle populations in Europe, Asia, and Canada have led to concern over the use of gelatin (a ruminant-derived protein) in human food and animal feed products. The present invention provides an attractive alternative to the use of gelatin to stabilize comestible particles.

The biomolecules, i.e., the proteinaceous film-forming component, may be modified to further improve crosslinking of the protein films. For example, the film-forming component (especially wheat gluten) may be treated with translutainase in order to reduce the susceptibility of the film-forming material to digestion by ruminal microorganisms.

Another aspect of the invention pertains to the encapsulation of selenium, an essential trace element. When fed to ruminant animals such as cattle and sheep, the microorganisms present in the rumen assimilate inorganic forms of selenium (such as sodium selenite or sodium selenite) and produce organic forms of the mineral, including selenomethionine and selenocysteine (selenium-based amino acids). Selenomethionine is considered to have relatively high bioavailability, while selenocysteine is considered to have more limited bioavailability. Sodium selenite and sodium selenate are substantially available for digestion by both ruminant and non-ruminant species. If inorganic forms of selenium are converted to selenocysteine, bioavailability may actually be reduced; consequently, encapsulation improves the overall bioavailability of selenium for ruminants.

The present invention is particularly useful in the encapsulation of vitamins to alter the site of digestion especially in ruminants, to enhance the stability of the vitamins for humans and livestock, to prevent mineral-induced oxidation of other nutrients, and to prevent ruminal microorganisms from converting the encapsulated nutrients from highly available forms to less available forms. A wide variety of materials may be encapsulated so as to alter the site of their digestion in the animal's digestive tract. These materials include fats, amino acids, peptides, proteins, carbohydrates, antimicrobial products, and enzymes. Microorganisms may also be encapsulated to alter the site of colonization or action in the digestive tract. Vaccines may be encapsulated so as to target specific sites of delivery and/or action. Leavening agents or other food additives may be encapsulated so as to promote the timely release of active compounds during selected points of manufacturing, processing, or preparation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following examples set forth preferred protein-based solutions that, when applied to feed ingredients and dried, will form protective coatings to facilitate altering of the site of digestion in ruminant animals. It is to be understood, however, that these examples are provided by way of illustration and nothing therein should be taken as a limitation upon the overall scope of the invention.

Example 1

This example describes the formation of a film-forming solution for use with the present invention. A film solution is prepared by mixing 18% (w/v) wheat gluten, 85 mL of 95% ethanol, 45 mL of distilled deionized water, and 6.2 g of glycerol in a beaker. The mixture is homogenized and placed onto a heated stir plate for 5 minutes. The acidity of the solution is adjusted to pH 3.3 using glacial acetic acid. The film-forming solution is sheared for 5-10 minutes using a Brink Homogenizer (setting 4). The solution is heated with continuous shearing to a final temperature of 80°C. Finally, the solution is centrifuged at 1000 x g for 5 minutes.

Example 2

This example describes the preparation of a film-forming solution in which a simple solvent is used that is readily recovered and re-utilized. Eighteen percent (18%) (w/v) of wheat protein isolate is gradually added to 5% acetic acid during continuous stirring (vortexing) on a low heat setting. The mixture is stirred until completely solubilized.

Example 3

This example describes the preparation of a ruminally protected feed ingredient. Approximately 30% (w/v) of a selected feed ingredient is mixed with a film-forming solution from either of Examples 1 or 2 above. The mixture is thoroughly homogenized and the resulting slurry poured into thin layers on aluminum trays. The trays are placed into a 50°C oven until dry. Alternatively, the product is spray dried or dried under a vacuum. The resulting product comprises the feed ingredient encapsulated by a thin proteinaceous film that is substantially resistant to ruminal degradation. The film solubilizes when subjected to low pH (approximately 1.5-2) in the abomasum, thereby rendering the encapsulated ingredients available for digestion in the post-ruminal tract.